

108TH CONGRESS  
1ST SESSION

# S. 1197

To amend the Public Health Service Act to ensure the safety and accuracy of medical imaging examinations and radiation therapy treatments.

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## IN THE SENATE OF THE UNITED STATES

JUNE 5, 2003

Mr. ENZI (for himself, Mr. KENNEDY, Mr. DASCHLE, Mr. LAUTENBERG, and Mr. DORGAN) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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## A BILL

To amend the Public Health Service Act to ensure the safety and accuracy of medical imaging examinations and radiation therapy treatments.

1       *Be it enacted by the Senate and House of Representa-*  
2       *tives of the United States of America in Congress assembled,*

3       **SECTION 1. SHORT TITLE.**

4       This Act may be cited as the “Consumer Assurance  
5       of Radiologic Excellence Act of 2003”.

6       **SEC. 2. FINDINGS AND PURPOSES.**

7       (a) FINDINGS.—Congress makes the following find-  
8       ings:

1           (1) More than 300,000,000 medical imaging ex-  
2           aminations and radiation therapy treatments are ad-  
3           ministered annually in the United States.

4           (2) Seven out of every 10 Americans undergo a  
5           medical imaging examination or radiation therapy  
6           treatment every year in the United States.

7           (3) The administration of medical imaging ex-  
8           aminations and radiation therapy treatments and  
9           the effect on individuals of such procedures have a  
10          substantial and direct effect upon public health and  
11          safety and upon interstate commerce.

12          (4) It is in the interest of public health and  
13          safety to minimize unnecessary or inappropriate ex-  
14          posure to radiation due to the performance of med-  
15          ical imaging and radiation therapy procedures by  
16          personnel lacking appropriate education and creden-  
17          tials.

18          (5) It is in the interest of public health and  
19          safety to have a continuing supply of adequately  
20          educated persons and appropriate accreditation and  
21          certification programs administered by State govern-  
22          ments.

23          (6) Persons who perform or plan medical imag-  
24          ing or radiation therapy, including those employed  
25          at Federal facilities or reimbursed by Federal health

1 programs, should be required to demonstrate com-  
2 petence by reason of education, training, and experi-  
3 ence.

4 (7) The protection of public health and safety  
5 from unnecessary or inappropriate medical imaging  
6 and radiation therapy procedures and the assurance  
7 of efficacious procedures are the responsibilities of  
8 both the State and the Federal Governments.

9 (8) Facilities that conduct medical imaging or  
10 radiation therapy engage in and affect interstate  
11 commerce. Patients travel regularly across State  
12 lines to receive medical imaging services or radiation  
13 therapy. Facilities that conduct medical imaging or  
14 radiation therapy engage technicians, physicians,  
15 and other staff in an interstate market, and pur-  
16 chase medical and other supplies in an interstate  
17 market.

18 (9) In 1981, Congress enacted the Consumer-  
19 Patient Radiation Health and Safety Act of 1981  
20 (Public Law 97-35) which established minimum  
21 Federal standards for the accreditation of education  
22 programs for persons who perform or plan medical  
23 imaging examinations and radiation therapy treat-  
24 ments and for the certification of such persons. The

1 Act also provided the States with a model State law  
2 for the licensing of such persons.

3 (10) Twenty-two years after the enactment of  
4 the Consumer-Patient Radiation Health and Safety  
5 Act of 1981—

6 (A) 13 States do not require licensure of  
7 any kind for persons who perform or plan med-  
8 ical imaging examinations and radiation ther-  
9 apy treatments;

10 (B) 37 States license, regulate, or register  
11 radiographers;

12 (C) 28 States license radiation therapists;

13 (D) 22 States license nuclear medicine  
14 technologists;

15 (E) 8 States license or require board cer-  
16 tification of medical physicists; and

17 (F) no States regulate or license medical  
18 dosimetrists.

19 (b) PURPOSES.—The purposes of this Act are—

20 (1) to ensure the accreditation of education pro-  
21 grams for, and the licensure or certification of, per-  
22 sons who perform, plan, evaluate, or verify patient  
23 dose for medical imaging examinations and radiation  
24 therapy treatments; and

1           (2) to ensure the safety and accuracy of med-  
2       ical imaging examinations and radiation therapy  
3       treatments.

4 **SEC. 3. QUALITY OF MEDICAL IMAGING AND RADIATION**  
5 **THERAPY.**

6       Part F of title III of the Public Health Service Act  
7       (42 U.S.C. 262 et seq.) is amended by adding at the end  
8       the following:

9       “Subpart 4—Medical Imaging and Radiation Therapy

10 **“SEC. 355. QUALITY OF MEDICAL IMAGING AND RADIATION**  
11 **THERAPY.**

12       “(a) IN GENERAL.—The Secretary shall establish  
13 standards to assure the safety and accuracy of medical  
14 imaging or radiation therapy. Such standards shall include  
15 licensure or certification, accreditation, and other require-  
16 ments determined by the Secretary to be appropriate.

17       “(b) EXEMPTIONS.—The standards established  
18 under subsection (a) shall not apply to physicians (as de-  
19 fined in section 1861(r) of the Social Security Act (42  
20 U.S.C. 1395x(r))), nurse practitioners and physician as-  
21 sistants (as defined in section 1861(aa)(5) of the Social  
22 Security Act (42 U.S.C. 1395x(aa)(5))).

23       “(c) REQUIREMENTS.—Under the standards estab-  
24 lished under subsection (a), the Secretary shall ensure

1 that individuals prior to performing or planning such im-  
2 aging or therapy—

3 “(1) have successfully completed a national ex-  
4 amination approved by the Secretary under sub-  
5 section (d) for individuals who perform or plan med-  
6 ical imaging or radiation therapy; and

7 “(2) meet such other requirements relating to  
8 medical imaging or radiation therapy as the Sec-  
9 retary may prescribe.

10 “(d) APPROVED BODIES.—

11 “(1) IN GENERAL.—The Secretary shall certify  
12 private nonprofit organizations or State agencies as  
13 approved bodies with respect to the accreditation of  
14 educational programs or the administration of ex-  
15 aminations to individuals for purposes of subsection  
16 (c)(1) if such organizations or agencies meet the  
17 standards established by the Secretary under para-  
18 graph (2) and provide the assurances required under  
19 paragraph (3).

20 “(2) STANDARDS.—The Secretary shall estab-  
21 lish minimum standards for the certification of ap-  
22 proved bodies under paragraph (1) (including stand-  
23 ards for recordkeeping, the approval of curricula and  
24 instructors, the charging of reasonable fees for ac-  
25 creditation or for undertaking examinations), and

1 other additional standards as the Secretary may re-  
 2 quire.

3 “(3) ASSURANCES.—To be certified as an ap-  
 4 proved body under paragraph (1), an organization or  
 5 agency shall provide the Secretary satisfactory as-  
 6 surances that the body will—

7 “(A) comply with the standards described  
 8 in paragraph (2);

9 “(B) notify the Secretary in a timely man-  
 10 ner before the approved body changes the  
 11 standards of the body; and

12 “(C) provide such other information as the  
 13 Secretary may require.

14 “(4) WITHDRAWAL OF APPROVAL.—

15 “(A) IN GENERAL.—The Secretary may  
 16 withdraw the certification of an approved body  
 17 if the Secretary determines the body does not  
 18 meet the standards under paragraph (2).

19 “(B) EFFECT OF WITHDRAWAL.—If the  
 20 Secretary withdraws the certification of an ap-  
 21 proved body under subparagraph (A), the ac-  
 22 creditation of an individual or the completion of  
 23 an examination administered by such body shall  
 24 continue in effect until the expiration of a rea-  
 25 sonable period, as determined by the Secretary,

1           for such individual to obtain another accredita-  
2           tion or to complete another examination.

3           “(e) EXISTING STATE STANDARDS.—Standards for  
4 the licensure or certification of personnel, accreditation of  
5 educational programs, or administration of examinations,  
6 established by a State prior to the effective date of the  
7 standards promulgated under this section, shall be deemed  
8 to be in compliance with the requirements of this section  
9 unless the Secretary determines that such State standards  
10 do not meet the minimum standards prescribed by the  
11 Secretary or are inconsistent with the purposes of this sec-  
12 tion.

13          “(f) EVALUATION AND REPORT.—The Secretary  
14 shall periodically evaluate the performance of each ap-  
15 proved body under subsection (d) at an interval deter-  
16 mined appropriate by the Secretary. The results of such  
17 evaluations shall be included as part of the report sub-  
18 mitted to the Committee on Health, Education, Labor,  
19 and Pensions of the Senate and the Committee on Energy  
20 and Commerce of the House of Representatives in accord-  
21 ance with 354(e)(6)(B).

22          “(g) DELIVERY OF AND PAYMENT FOR SERVICES.—  
23 Not later than 18 months after the date of enactment of  
24 this section, the Secretary shall promulgate regulations to  
25 ensure that all programs that involve the performance of



1 or payment for medical imaging or radiation therapy, that  
 2 are under the authority of the Secretary, are performed  
 3 in accordance with the standards established under this  
 4 section.

5 “(h) ALTERNATIVE STANDARDS FOR RURAL  
 6 AREAS.—The Secretary shall determine whether the  
 7 standards developed under subsection (a) must be met in  
 8 their entirety with respect to payment for medical imaging  
 9 or radiation therapy that is performed in a geographic  
 10 area that is determined by the Medicare Geographic Clas-  
 11 sification Review Board to be a ‘rural area’. If the Sec-  
 12 retary determines that alternative standards for such rural  
 13 areas are appropriate to assure access to quality medical  
 14 imaging, the Secretary is authorized to develop such alter-  
 15 native standards. Alternative standards developed under  
 16 this subsection shall apply in rural areas to the same ex-  
 17 tent and in the same manner as standards developed  
 18 under subsection (a) apply in other areas.

19 “(i) REGULATIONS.—Not later than 18 months after  
 20 the date of enactment of this section, the Secretary shall  
 21 promulgate such regulations as may be necessary to imple-  
 22 ment this section.

23 “(j) DEFINITIONS.—In this section:

24 “(1) APPROVED BODY.—The term ‘approved  
 25 body’ means a nonprofit organization or State agen-

1 cy that has been certified by the Secretary under  
2 subsection (d)(1) to accredit or administer examina-  
3 tions to individuals who perform or plan medical im-  
4 aging or radiation therapy.

5 “(2) MEDICAL IMAGING.—The term ‘medical  
6 imaging’ means any procedure or article, excluding  
7 medical ultrasound procedures, intended for use in  
8 the diagnosis or treatment of disease or other med-  
9 ical or chiropractic conditions in humans, including  
10 diagnostic X-rays, nuclear medicine, and magnetic  
11 resonance procedures.

12 “(3) PERFORM.—The term ‘perform’, with re-  
13 spect to medical imaging or radiation therapy,  
14 means—

15 “(A) the act of directly exposing a patient  
16 to radiation via ionizing or radio frequency ra-  
17 diation or to a magnetic field for purposes of  
18 medical imaging or for purposes of radiation  
19 therapy; and

20 “(B) the act of positioning a patient to re-  
21 ceive such an exposure.

22 “(4) PLAN.—The term ‘plan’ with respect to  
23 medical imaging or radiation therapy, means the act  
24 of preparing for the performance of such a proce-  
25 dure to a patient by evaluating site-specific informa-

1       tion, based on measurement and verification of radi-  
2       ation dose distribution, computer analysis, or direct  
3       measurement of dose, in order to customize the pro-  
4       cedure for the patient.

5           “(5) RADIATION THERAPY.—The term ‘radi-  
6       ation therapy’, means any procedure or article in-  
7       tended for use in the cure, mitigation, treatment, or  
8       prevention of disease in humans that achieves its in-  
9       tended purpose through the emission of radiation.”.

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